**Research Ethics Board**

**Change in Study Personnel Amendment Form**

**Please submit the signed and scanned application form and accompanying documents to** **reb@hrh.ca****. In the email subject line, please include the REB number and the type of submission.**

**SECTION 1: Study Identification**

|  |  |  |  |
| --- | --- | --- | --- |
| HRH REB Number: |       | Principal Investigator: |       |
| Sponsor/Funder: |       | Expiry Date: |       |
| Study Title: |       |

|  |  |
| --- | --- |
| Name of Person Competing the Form: |       |
| Telephone Number: |       |
| Email Address: |       |

**SECTION 2: Change of Study Personnel**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Add | Drop | Personnel Name | Credentials | Role in Study |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |
| [ ]  | [ ]  |       |       |       |

**Effective Date of Change** (dd/mmm/yyyy):

**SECTION 3: Documents**

**Submit any documents affected by this change. Highlight the changes (both additional and deletions) and also include a clean copy of the document.**

[ ]  Consent Form(s)

[ ]  Wallet Card(s)

[ ]  Other:

**SECTION 4: Questions**

|  |  |  |  |
| --- | --- | --- | --- |
| Is the outgoing PI leaving HRH? | [ ]  Yes | [ ]  No | [ ]  N/A |
| Does this change affect any other REB files? If yes, submit a separate form for each study. |  [ ]  Yes | [ ]  No | [ ]  N/A |
| Has Contracts been notified of this change? | [ ]  Yes | [ ]  No | [ ]  N/A |
| Will participants be notified of this change? | [ ]  Yes | [ ]  No | [ ]  N/A |

**SECTION 5: Updated to the HRH Initial Prospective REB Application**

Numbers in brackets reference the question number in the application.

|  |  |
| --- | --- |
| (8) | Do any of the conflicts listed below apply to any of the new personnel involved in the research study or any member of their immediate family? If Yes, indicate which conflicts apply and append a letter to the Chair of the REB detailing these activities and how they will be managed. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflict of interest may also arise with regard to the disclosure of personal health information.[ ]  Function as an advisor, employee, officer, director or consultant to sponsor[ ]  Have direct or indirect financial interest in the drug, device, or technology[ ]  Receive an honorarium[ ]  Receive direct or indirect financial benefit from disclosure of personal health information[ ]  Other:[ ]  None of the above |

|  |  |
| --- | --- |
| (18D) | Will new personnel be reviewing health records/identifying information for recruitment purpose?[ ]  Yes [ ]  No [ ]  N/A |
| (18Ei) | Will new study personnel be obtaining consent?[ ]  Yes [ ]  No [ ]  N/AIf Yes, please indicate if there is any relationship with the participants and describe what steps will be taken to avoid the perception of undue influence.      |
|  |  |
| (23A) | Will new personnel have access to the personal health information?[ ]  Yes [ ]  No [ ]  N/A |

**SECTION 6: Signatures**

**6. a) Signatures for Change of Principal Investigator**

**Outgoing Principal Investigator Statement**

I will no longer assume the role of Principal Investigator for this study and hand over the responsibility of the study conduct to the person named below as the Incoming Principal Investigator.

Print Name Signature Date (dd/mmm/yyyy)

**Incoming Principal Investigator**

I assume full responsibility for the scientific and ethical conduct of the study as approved by the REB and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethics Conduct for Research Involving Human Participants and any other relevant regulations or guidelines. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project.

Print Name Signature Date (dd/mmm/yyyy)

**Department/Division/Program Head for Incoming Principal Investigator**

I am aware of this change in personnel. I consider it to be feasible and appropriate. I attest that the Principal Investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study.

Print Name Signature Date (dd/mmm/yyyy)

**6. b) Signature for Change in Co-Investigator**

**Incoming Co-Investigator**

I agree to participate in this study as approved by the REB and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Participants and any other relevant regulations or guidelines.

Print Name Signature Date (dd/mmm/yyyy)

**6. c) Signature of Principal Investigator for Staff Changes**

**Current Principal Investigator**

This signature attests that the Principal Investigator has assessed the safety implications of this amendment, its impact on study procedures and is prepared to take any necessary steps to implement the change(s). Further, the Principal Investigator will not implement any changes to, or deviations from the protocol without Research Ethics Board approval except to eliminate an immediate hazard to study participants or when changes involve only logistical or administrative aspects of the study.

Print Name Signature Date (dd/mmm/yyyy)

**Section 7: Contact Information of Incoming Study Personnel**

**Incoming Principal Investigator:**

|  |  |
| --- | --- |
| Department/Division/Program: |       |
| Telephone Number: |       | Fax Number: |       |
| Email Address: |       |

**Incoming Co-Investigator:**

|  |  |
| --- | --- |
| Department/Division/Program: |       |
| Telephone Number: |       | Fax Number: |       |
| Email Address: |       |

**Incoming Study Coordinator:**

|  |  |
| --- | --- |
| Department/Division/Program: |       |
| Telephone Number: |       | Fax Number: |       |
| Email Address: |       |